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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ERIC T. KOOL

Appeal 2008-2113
Application 10/604,400
Technology Center 1600

Oral Hearing Held: May 20, 2008

Before DONALD E. ADAMS, LORA M. GREEN, and FRANCISCO C. PRATS, *Administrative Patent Judges.*

ON BEHALF OF THE APPELLANT:

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The hearing in the above-entitled came on for hearing on Tuesday, May 20, 2008, commencing at 1:00 p.m., at The U.S. Patent and Trademark

Office, 600 Dulany Street, Alexandria, Virginia, before Deborah Rinaldo, RPR, Notary Public Registration No. 292810.

P R O C E E D I N G S

JUDGE ADAMS: Good afternoon. Welcome to the Board. We are familiar with your issue and if you'll start by spelling your name into the record and introducing your colleague.

MS. WAACK: Is there a speaker I should speak from or if I just speak at the podium you can hear me?

JUDGE ADAMS: You can sit, stand. Doesn't matter to me.

MS. WAACK: My name is Janelle Waack. It's spelled J-A-N-E-L-L-E, last name W-A-A-C-K. I'm with Howrey, LLP. That's H-O-W-R-E-Y. I'm appearing on behalf of applicant Kool for the patent application that is assigned to the board of trustees of Stanford University.

And with me today is Dr. Wendy Davis, W-E-N-D-Y, D-A-V-I-S. She is a patent agent with Howrey, LLP.

May I begin?

JUDGE ADAMS: Absolutely. You are already two minutes in.

MS. WAACK: This appeal focuses on two anticipation rejections under 35 U.S.C. 102(b). The two pieces of prior art that were used as a basis for the two rejections are Livak and Xu. It's spelled X-U. I say Xu or Xu.

Claim 1 is the one we can focus on for this hearing. Claim 1 states a composition comprising a fluorophore compound, the fluorophore compound comprising a fluorophore group and a fluorescence quenching leaving group.

The main point here is neither Livak nor Xu teaches a fluorescence quenching leaving group. Livak and Xu do disclose a quenching group but not a quenching group that also acts as a leaving group.

JUDGE ADAMS: What does it mean to be a leaving group?

MS. WAACK: I'm sorry, I was on an airplane and my hearing is not as good --

JUDGE ADAMS: What does it mean to be a leaving group?

MS. WAACK: It is a compound that actually leaves.

JUDGE ADAMS: Leaves what?

MS. WAACK: It is chemically bonded and the chemical bond is broken and it leaves. In this case it is a fluorophore compound and that is defined in the specification at paragraph 21. That's a summary of the invention. And it says oligonucleotides containing a --

JUDGE ADAMS: Paragraph 21 of the specification?

MS. WAACK: Paragraph 21 of the specification. I'm referring to the published application. That may throw off the paragraph numbering. Should I find the -- it's the summary of the invention. It's rather short in this case.

JUDGE ADAMS: Okay.

MS. WAACK: There we see oligonucleotides containing a fluorophore and a specialized quencher that also acts as a leaving group R disclosed.

So what you have is an oligonucleotide --

JUDGE GREEN: But there's nothing in the claim that requires an oligonucleotide, correct?

MS. WAACK: What the claim says is a composition comprising a fluorophore compound. And that compound is defined and used in the specification to include the basic oligonucleotide.

JUDGE GREEN: But I'm just saying we're not limited to oligonucleotides. Basically this compound could be anything that has a fluorophore on it and the fluorescence quenching group on it?

MS. WAACK: Within -- it has to be read in light of the specification.

JUDGE GREEN: But compound -- you have to read in light of the specification but you don't import limitations into the claims from the specification. If you wanted oligo, you should have said oligo. Compound can be anything, correct?

MS. WAACK: Your Honor, you are right that oligonucleotide, that word does not appear in the claim. But when you read the claim in light of the specification --

JUDGE ADAMS: Wait. Oligonucleotide is a nucleic acid, right?

MS. WAACK: Yes.

JUDGE ADAMS: Read claim 6.

MS. WAACK: Claim?

JUDGE ADAMS: Your claim 6.

JUDGE GREEN: And claim 5.

MS. WAACK: Claim 6: The compound of claim 1 wherein the fluorophore compound is a nucleic acid.

JUDGE ADAMS: What's claim 5 say?

MS. WAACK: Claim 5 says, the composition of claim 1 wherein the fluorophore compound is an organic compound and organometallic compound, a nucleic acid, a peptide, a protein, a lipid or a carbohydrate.

JUDGE ADAMS: So you are saying when read in light of the specification, claim 1 means what?

MS. WAACK: I'm sorry. I'm having a little bit of trouble hearing.

JUDGE ADAMS: You said when read in light of the specification, claim 1 means what?

MS. WAACK: My point was, it says an oligonucleotide having the fluorophore -- I'm sorry.

Claim 1 says a fluorophore compound comprising a fluorophore group and a fluorescence quenching leaving group.

My point is there is a basic compound there such as an oligonucleotide and attached to that are a fluorophore group and a fluorescence quenching leaving group.

And when you asked the question, what is leaving, here it would be if the basic compound is an oligonucleotide, the fluorescence quenching leaving group is leaving the oligonucleotide.

JUDGE ADAMS: What is it in that claim that requires only this fluorescence quenching leaving group to leave? Couldn't that fluorescence quenching leaving group be attached to the, for example, oligonucleotide and half of that oligonucleotide be cut from the rest and it leave with the rest of that molecule?

MS. WAACK: What the claim says is, "and a fluorescence quenching leaving group." So it's that part of the compound that does the fluorescence quenching that is leaving. There are several --

JUDGE ADAMS: Well, that's what I'm getting to. Is it just that fluorescence quenching leaving group or can that fluorescence quenching leaving group be attached to something and together they leave?

JUDGE GREEN: Because it's the functionality, it's the quenching that leaves. There's nothing in the claim that limits it to just the quenching group itself that may be attached to something like a peptide or an oligonucleotide or a lipid. If it takes part of the lipid with it or the part of the oligo with it or part of the protein with it, I don't see anything in your claim that prevents that as long as the quenching leaves.

MS. WAACK: What the claim says is a fluorescence quenching leaving group. Our interpretation is that what is leaving is that portion that causes the fluorescence quenching. And if you look in the specification, there are some specific examples of what that is.

JUDGE ADAMS: Show me.

MS. WAACK: For example, look at the figure 1. Figure 1 is a simplified form of that. If you look at figure 1, there's a compound, a bond with an X. That X is defined in the specification as the fluorescence quenching leaving group.

And then when you move to the second part of that figure, the bond between the X and the rest of the compound is now gone, and that shows the X or the fluorescence quenching group leaving. And that's why we refer to it as the fluorescence quenching leaving group.

JUDGE GREEN: But that is just one particular embodiment of your invention because figure 1, the -- it says for the detection of a DNA sequence. So your claims are not limited to that embodiment.

I'm looking at your specification. Brief description of the drawings it says, Figure 1 shows the detection of the DNA sequence of interest using two nucleic acid probes.

So all I'm saying is that is one embodiment of your invention.

MS. WAACK: But I think that figure is consistent with our interpretation that, going back to the original question from Judge Adams, when you are asking what is leaving, it's that part that is causing the fluorescence quenching.

In the figure it's represented as X and it's X that is leaving.

JUDGE ADAMS: Let's take a look at figure 1 of Livak.

MS. WAACK: Okay. I'm there.

JUDGE ADAMS: You are familiar with Livak. So we have R, some fluorophore compound; and we have Q, subquenching group, right?

MS. WAACK: Yes.

JUDGE ADAMS: And if you look at where -- the third part down, cleavage, you see R is no longer associated with Q.

MS. WAACK: Right.

JUDGE ADAMS: Q left. Q left R.

MS. WAACK: Q and R are no longer in the same compound but that's because it was R that left.

JUDGE GREEN: But isn't that just semantics? Does it really matter whether R left or Q left? All we're claiming is the compound? We're not

claiming a method. And there's nothing in the claim that requires Q to remain associated with the DNA complex.

MS. WAACK: I don't believe that is the case.

JUDGE GREEN: But you do agree that it is the position of the office that we give claims their broadest reasonable interpretation?

MS. WAACK: Yes. Those words are used in defining what applies for claim construction. But another part of claim construction is also reading the claims in light of the specification.

And I mean, I think your question gets to the heart of the matter here. We've got the Kool invention and this idea of having compounds such as oligonucleotides that want to make use of fluorescence activity to measure something physically happening in the system.

JUDGE ADAMS: Wait. Before we go there, take me back to figure 1 of Livak. Livak has an oligonucleotide with an R group of fluorophore and a Q group, a quenching group, right?

MS. WAACK: Yes.

JUDGE ADAMS: So for all intents and purposes, what's the difference between this oligonucleotide with an R and Q talked about in Livak and your claimed invention but for these two words, "leaving group"?

MS. WAACK: The difference is what is leaving the compound.

JUDGE GREEN: But that goes to method of use. What we have is a compound with a fluorophore and a quenching group on it wherein something is capable of leaving by cleavage or whatever else. But in the end all you are claiming is a compound with a fluorophore and a quenching group on it.

MS. WAACK: But there is this basic compound.

JUDGE GREEN: Why couldn't this serve as a leaving group if they were to do a slightly different chemistry in the method of Livak?

MS. WAACK: I'm not quite hearing your question.

JUDGE GREEN: In the method of Livak, why couldn't Q be the one that's leaving if they use different chemistries?

MS. WAACK: That's not what is disclosed in Livak.

JUDGE GREEN: No. We're talking about a compound. We're -- the compound may have the inherent property that if you treated this with different chemistry, that Q could leave.

I think that's why Judge Adams is saying leave "leaving group" out of it and we have a claim to a compound with a fluorescein and a quenching group. How does your compound differ from the compound of Livak without getting into its method of use?

MS. WAACK: Because in Livak the fluorescent reporter dye is leaving.

JUDGE GREEN: So you can't tell me how it's different?

MS. WAACK: In the Kool invention the fluorescence quenching leaving group is leaving.

JUDGE GREEN: So you can't tell me how it's different without getting into its method of use?

MS. WAACK: No, that's not the case at all. You have to know what is your fluorophore group and what is your fluorescence quenching group. If it's that part of the compound causing the fluorescence the fluorophore

group to leave the rest of the compound, that one moves off, that's the leaving group.

If your compound is here and the portion --

JUDGE ADAMS: No. Stop. I have an oligonucleotide. At one end I have one. At the other end I have two. I'm not using it for anything. I've just got them sitting there in solution and I cut them in half. Which one left?

MS. WAACK: Where do you do your ligation?

JUDGE ADAMS: Which one left? It doesn't matter what I did with anything. I have them in solution. Claim 1 is a composition. I've got this thing in solution. I cut it in half. Tell me which one left.

MS. WAACK: All I can say is the fluorophore group and the fluorescence quenching group are no longer within the same compound. But that's not what we're talking about in these claims here.

JUDGE ADAMS: That's exactly what you are talking about. Where is the ligation in claim 1?

MS. WAACK: The ligation is between the fluorescence quenching group --

JUDGE ADAMS: Where does it say ligation in claim 1?

MS. WAACK: Because we talk about a leaving group. Leaving group implies that you have an original compound and a fluorescence quenching group is chemically bonded to it, and at some point there's a ligation.

JUDGE ADAMS: That's not implied to me. Show me where that's disclosed.

MS. WAACK: A leaving group is something that leaves.

JUDGE ADAMS: I have a molecule that has R on one side and Q on the other and I cut it in half. Which one left?

MS. WAACK: They are both still attached to parts of the compound.

JUDGE ADAMS: So how does your claim differ from that?

MS. WAACK: Because it says a composition comprising of fluorophore compound, that's the whole compound, and the fluorophore compound comprises the fluorophore group and the fluorescence quenching leaving group.

What that means is your composition must be such that that fluorescence quenching group leaves the compound.

JUDGE ADAMS: And the compound remains intact?

MS. WAACK: The fluorescence quenching group leaves and the remainder --

JUDGE ADAMS: And the remainder of the compound remains intact?

MS. WAACK: Yes.

JUDGE ADAMS: Where is that supported in your spec?

MS. WAACK: That's the whole heart of the invention.

JUDGE ADAMS: Show me some place in your specification that supports your argument.

MS. WAACK: Again, I'm referring to the published application. When Kool presented his application to the patent office, he provided a background and I think that's pretty useful in this situation.

The Kool specification begins with an abstract. And the first sentence is: Novel compounds having a fluorescence quencher as a leaving group are disclosed.

That's the key to this whole thing.

JUDGE ADAMS: That doesn't answer my question.

MS. WAACK: But I'm pointing out the parts of the specification --

JUDGE ADAMS: You have four minutes to make your point.

MS. WAACK: Okay. I have more. We have novel compounds having a fluorescence quencher as a leaving group. That's consistent with the construction I'm advocating.

Also, if you go to the summary of the invention, oligonucleotides containing a fluorophore and a specialized quencher that also acts as a leaving group are disclosed.

The key here is this is different than the prior art. The prior art was other compounds that had a quencher and a leaving group on them.

For example, if you look at paragraph 12 in the published specification they talk about molecular beacons which are a compound that has both a fluorophore and a quencher. In there the compound is shaped as a hair pin.

When the hair pin is closed, the fluorophore and the quencher are together. So the quencher is suppressing the fluorescence. When it goes to the reaction, the compound opens up. The hair pin is open and then the fluorophore and the quencher move apart.

So we know that in the prior art are these compounds that have attached a fluorophore and a quencher. Kool comes in and says I can do

something different and better. Under my invention I have a composition in which you have your basic compound with a fluorophore compound and with the fluorescence quenching group. In my compound that quenching group has the ability to leave. And that's why I'm different and novel over the prior art.

And that's the same reasoning why he is novel and different over Livak and Xu.

JUDGE ADAMS: I understand what you are saying. I'm still waiting for you to show me something in your specification that says what you are saying. You showed me the first line of your spec. Great. You showed me the prior art at paragraph 12. Great.

Show me where your specification says what you are saying, that it's only the quenching group that is leaving and the remainder of the compound stays the same.

MS. WAACK: I think that was clearly depicted in figure 1 with X representing the quenching group. And I think the language is very clear here that the oligonucleotides containing a fluorophore specialized quencher that also acts as a leaving group.

They are talking about the specialized quencher, and it's the specialized quencher that's the leaving group. There's nothing inconsistent with that statement. It is the specialized quencher that acts as a leaving group.

JUDGE ADAMS: Any other arguments?

MS. WAACK: I do want to point out a couple more things. I think there's a fundamental technical error in the examiner's analysis and it's this.

The examiner is arguing, looking at Livak and Xu and seeing compounds that have attached a fluorophore and a quencher, and the examiner looks at those prior art compounds and says under a, quote, proper set of chemical conditions with a, quote, proper nucleophile, the fluorescence quencher, quote, might leave.

That's pure speculation. There is nothing in either of those references that states that there are these certain conditions out there under which the fluorescence quencher might leave. That's purely the examiner's statement and that's pure speculation.

The examiner has not identified what is a proper set of chemical conditions or what is a proper nucleophile. And just by using the word "might," the examiner is acknowledging she can't confirm that that is or is not happening in the reference. It's purely the examiner's speculation.

And moreover, the argument that the Livak and Xu references disclose a compound in which the fluorescence quenching group might leave is contradicted by the record because we have a number of references, including Livak and Xu, where you have a compound where the fluorescence quenching group does not leave.

JUDGE GREEN: I just have one quick question. All I have is the specification as filed. In paragraph 81, one of the quenchers, is TAMRA a quencher or is that -- TAMRA is a quencher, correct?

MS. WAACK: I need to look at that. It's a fluorophore group.

JUDGE ADAMS: I just need to point out you are out of time. I'll give you another minute or so to wrap it up.

MS. WAACK: Thank you. Another main point here, in addition to this technical error, what the examiner is essentially doing by arguing anticipation in terms of claim construction is trying to rewrite the claim.

What the examiner wants to do is take that claim term "fluorescence quenching leaving group" and strike the word "leaving" from it.

You clearly cannot do that in claim construction. That's not permissible. You cannot go in and strike a word from the claim. And I think that's at the heart of what the examiner is trying to do, say, well, I didn't see it in the prior art, but eventually it will leave.

The examiner even goes on at one point and says it might leave at that point or it might leave a year from now. As long as it leaves in some fashion, somehow the claim has to be construed that way.

And I think that's not a technically sound proposition. And if you leave all the words in the claim, including "fluorescence quenching leaving group," you will find that it defines above and over the Livak and Xu references, and the rejections should be withdrawn.

JUDGE ADAMS: Thank you.

(Whereupon, the proceedings at 1:23 p.m. were concluded.)